

**TOXIC SUBSTANCE CONTROL ACT (TSCA)  
§8(e) Substantial Risk Information – General  
Awareness and DuPont Review Process**

**STANDARDIZED SHE MANDATED TRAINING MODULE  
FOR U.S. MANUFACTURING SITES**



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EXHIBIT #

DEPONENT



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# *TSCA §8(e) Substantial Risk Information*

## *General Awareness & Procedure for Internal Review*

Introduction: This TSCA §8(e) Training will provide

1. an overview of TSCA §8(e) and
2. an overview of the process to be followed within DuPont for submitting potential TSCA §8(e) information for review.

Frequency: Upon initial employment, with annual reminder thereafter.

Regulatory Reference: 15 USC §2607, TSCA §8(e); 68 FR 33129 (June 3, 2003)

Company Standard: S4V - Notification of Substantial Risk under §8(e) the U.S. Toxic Substances Control Act

Who Must Be Trained: All employees.

## Learning Objectives

Upon completion of this course, each employee should:

- Have a general understanding of the TSCA §8(e) Substantial Risk Information statute.
- Recognize the types of information that might be reportable.  
*Note: This course is not designed to make you expert on what information is actually reportable under TSCA §8(e).*
- Understand how and where to submit potential substantial risk information for internal DuPont review.
- Understand the penalties for failure to comply with TSCA §8(e).
- Understand your rights with respect to TSCA §8(e).

## *Course Outline (Key Topics)*

1. Overview of TSCA §8(e)
2. What is NOT Substantial Risk Information under TSCA §8(e)?
3. What might be Substantial Risk Information under TSCA §8(e) and should be submitted for internal DuPont review?
4. How to Report Internally and to Whom
5. Penalties for Failure to Comply
6. Notifying the Submitter of the Reporting Decision and Rights under TSCA §8(e)

# TSCA Section 8(e) - General Awareness

## Purpose of this Training

- §8(e) of the Toxic Substances Control Act (TSCA) requires reporting to the US Environmental Protection Agency (EPA) of what is referred to as *“substantial risk information”*
- Individual employees and officers have an obligation to report such information directly to EPA and can be held personally liable for failure to report EXCEPT where a Company has established, internally publicized, and implemented procedures for employee submission and processing of such information AND the employee submits the information through that process.
- This Training provides
  1. an overview of TSCA §8(e) and
  2. a description of the procedure that has been established for employees to submit potential TSCA §8(e) information for review

# 1. Overview of TSCA §8(e) statute

TSCA §8(e) requires that

- any *person* who manufactures (includes imports), processes, or distributes in commerce a chemical substance or mixture and
- who obtains information which reasonably supports the conclusion that the substance or mixture presents a substantial risk of injury to health or the environment shall
- immediately inform the EPA of such information, unless the person has actual knowledge that EPA has been adequately informed.

“Person” includes the Company and employees of the Company

## 1. Overview of TSCA §8(e) statute (cont)

- Impurities, by-products, R&D substances are NOT excluded
- TSCA broadly defines chemical substances and mixtures
- TSCA does not include substances with uses regulated only under the Federal Fungicide Insecticide Rodenticide Act (FIFRA) and/or the Federal Food Drug & Cosmetic Act (FFDCA)

TSCA §8(e) is a US law – BUT information available outside the US may be reportable if it becomes known by a US employee and if it pertains to a chemical substance or mixture that DuPont manufactures, imports, processes, or distributes in commerce in the US.

## 2. *What is NOT Substantial Risk Information?*

- Information is NOT reportable under TSCA §8(e) if it is already known to EPA.
- Information is considered known to EPA and NOT reportable if it is obtained in its entirety from one of the following sources:
  - ✓ An EPA study or report
  - ✓ Scientific publications, including bibliographic databases, available electronically or in hard copy
  - ✓ Scientific databases (e.g., Chemical Abstracts, Agricola, Index Medicus, Dissertation Abstracts, Biological Abstracts, etc.)
  - ✓ A news publication with circulation in the US
  - ✓ A radio or television news report broadcast in the US
  - ✓ A public scientific conference sponsored or co-sponsored by EPA



### 3. *What might be Substantial Risk Information?*

- The information need not be conclusive of substantial risk
- “Substantial risk” information falls into 3 categories:
  - ✓ Human health effects
  - ✓ Environmental contamination - emergency situations
  - ✓ Environmental contamination – non-emergency situations
- Each category is broadly covered in the charts that follow. For additional detail, consult the SHE manager or TSCA Coordinator for your business or function.
- *Information that might be Substantial Risk Information should be submitted for internal DuPont review (covered in later charts).*

### 3. *What might be “substantial risk” information? (cont)*

#### *✓ Human Health Effects*

- Any instance (including a single instance) of cancer, birth defects, mutagenicity, death, or serious or prolonged incapacitation, including the loss of or inability to use a normal bodily function with a consequent relatively serious impairment of normal activities, if one or a few chemicals appears to be strongly implicated
  - Any pattern of effects or evidence potentially showing that the chemical substance or mixture can produce cancer, mutation, birth defects or toxic effects resulting in death, or serious or prolonged incapacitation.
- ✓ Note:* Biomonitoring data (e.g., blood serum data) should be recognized as needing review, even if there is no adverse effect.

### 3. *What might be “substantial risk” information? (cont)*

#### ✓ *Environmental Contamination - emergency situations*

Any environmental contamination by a chemical substance or mixture to which an adverse effects (in animals or humans) has been ascribed and which

1. *seriously threatens humans with cancer, birth defects, mutation, death or serious or prolonged incapacitation, or*
  2. *seriously threatens non-human organisms with large-scale or ecologically significant population destruction,*
- should be reviewed.*

*Note: Emergency incidents of environmental contamination reported to the National Response Center are considered known to EPA and need not also be reported under TSCA §8(e).*

### 3. *What might be “substantial risk” information? (cont)*

#### ✓ *Environmental Contamination - non-emergency situations*

The following are the 5 categories of non-emergency situations involving environmental contamination:

- A. Non-emergency situations of chemical contamination involving humans and/or the environment
- B. Pronounced bioaccumulation
- C. Non-trivial adverse effects
- D. Ecologically significant changes in species' interrelationships
- E. Transformation or degradation to certain type of chemical

*Each of these situations is covered in more detail on slides that follow.*

### 3. *What might be “substantial risk” information? (cont)*

#### ✓ *Environmental Contamination - non-emergency situations*

#### *A. Non-emergency situations of chemical contamination involving humans and/or the environment*

Information that pertains to widespread and previously unsuspected distribution in environmental media of a chemical or substance known to cause serious adverse effects, when coupled with information that widespread or significant exposure to humans or non human organisms has occurred or is likely to occur should be reviewed.

- *Example:* Chemical A is a known animal carcinogen. Chemical A is discharged from Company X's outfall to a drinking water source. Humans are likely exposed to Chemical A via the drinking water. Regulatory agencies are not aware of the discharge. This type of information should be submitted for internal review.
- *Note:* information about contamination found at or below EPA established benchmark levels is not reportable; examples of such benchmarks are Maximum Contaminant Levels (MCLs) in drinking water, Ambient Water Quality Criteria for receiving bodies of water, Reference Doses (RfDs) or Concentrations (RfCs)
- *Note:* there are other exemptions to the reporting requirements for this type of information. Consult the SHE manager or TSCA Coordinator for your business or function for further details.

### 3. What might be “substantial risk” information? (cont)

- ✓ *Environmental Contamination - non-emergency situations*

#### *B. Pronounced Bioaccumulation*

Measurements and indicators of pronounced bioaccumulation previously unknown to EPA

*(including bioaccumulation in fish beyond 5,000 times water concentrations in a 30-day exposure or having an n-octanol water partition coefficient greater than 25,000)*

when coupled with potential for widespread exposure and any non-trivial adverse effect should be reviewed.

### 3. *What might be “substantial risk” information? (cont)*

✓ *Environmental Contamination - non-emergency situations*

#### C. Non-trivial adverse effects

Any non-trivial adverse effect, previously unknown to EPA,

*associated with a chemical known to have bioaccumulated to a pronounced degree or to be widespread in environmental media,*

should be reviewed.

### 3. What might be “substantial risk” information? (cont)

#### ✓ *Environmental Contamination - non-emergency situations*

#### D. Ecologically significant changes in species' interrelationships

Ecologically significant changes in species' interrelationships; that is, changes in population behavior, growth, survival, etc. that in turn affect other species' behavior, growth, or survival, should be reviewed.

#### *Examples include*

- *excessive stimulation of primary producers (algae, macrophytes) in aquatic ecosystems, e.g., resulting in nutrient enrichment, or eutrophication, of aquatic ecosystems*
- *interference with critical biogeochemical cycles, such as the nitrogen cycle*



### 3. *What might be “substantial risk” information? (cont)*

✓ *Environmental Contamination - non-emergency situations*

E. Transformation or degradation to certain type of chemical

Transformation or degradation to a chemical having an unacceptable risk that occurs easily should be reviewed.

### 3. What might be “substantial risk” information? (cont)

#### What are Sources of potentially reportable substantial risk information?

- Designed studies or undesigned, uncontrolled circumstances. *(There is no requirement that the information arise from a designed study.)*
- Reports, BUT ... information need not be in the form of a report.
- Results, BUT ... results need not be final. Preliminary results may be reportable.
- Information need not be generated by DuPont. Potentially reportable information could originate from 3<sup>rd</sup> parties (e.g., opposing counsel in litigation, trade associations, joint development partners, customers, etc.).
- Information need not be generated in the US.

### 3. What might be “substantial risk” information? (cont)

Examples of sources of potentially reportable TSCA §8(e) information:

- Designed controlled studies, including
  - ✓ toxicology studies
  - ✓ epidemiological studies
  - ✓ environmental monitoring studies
- Undesigned, uncontrolled circumstances, including
  - ✓ medical and health surveys,
  - ✓ clinical studies,
  - ✓ reports concerning and evidence of effects in consumers or workers,
  - ✓ medical hotline calls,
  - ✓ medical records,
  - ✓ TSCA §8(c) allegations

### 3. *What might be “substantial risk” information? (cont)*

Additional examples of sources of potentially reportable TSCA §8(e) information are as follows:

- Employee, neighbor, or customer concerns
- Human biological sample results, including worker and community member sample results and sample results received from litigation
- Previously unknown contamination information on products
- Product characterization studies (including degradation, decomposition, and pyrolysis studies)
- Environmental remediation activities
- Environmental incidents and emergencies
- Off-site environmental sampling results, including drinking water contamination and including sampling results received via litigation.

### 3. What might be “substantial risk” information? (cont)

#### Type of information that must be reviewed

- *If in doubt* about whether or not the information should be submitted for internal review by the Corporate TSCA §8(e) Review Team, then submit the information as instructed on the charts that follow. It is better to over-report than to not report.
- Additional guidance/discussion on what type of information is potentially reportable can be obtained from any TSCA §8(e) Review Team member (see next chart) or from any TSCA SBU Coordinator.
- The TSCA SBU Coordinators are listed on the DuPont intranet under SHE, then click Regulatory, then click TSCA, then click TSCA Coordinators Network

## *4. How to Report Internally and to Whom?*

- Complete page 1 of the TSCA §8(e) Potential Reportable form and submit, preferably electronically, as directed on the form.
- The most current form can be found on the DuPont Intranet site: *click on SHE, then on Regulatory, then on TSCA, then on TSCA 8(e) non-Haskell Potential Reportable Notification form*

*(see screen shots that follow)*



## 4. How to Report Internally and to Whom?

The most current form can be found on the DuPont Intranet site: click on 1) SHE, then on 2) Regulatory, then on 3) TSCA, then on 4) TSCA 8(e) non-Haskell Potential Reportable Notification form

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INTERNAL USE ONLY

1

2

## 4. How to Report Internally and to Whom?

The most current form can be found on the DuPont Intranet site: *click on 1) SHE, then on 2) Regulatory, then on 3) TSCA, then on 4) TSCA 8(e) non-Haskell Potential Reportable Notification form*

**DU PONT** Global SHE

REG

Content Owner: Julie Dixon

DuPont Environmental Regulatory Communications

Distribution Regulatory Guidance

Product Stewardship Regulatory Issues

Hazard Communication

SCA

External Regulatory Links

- [Federal Register](#)
- [Code of Federal Regulations](#)
- [Environmental Protection Agency](#)
- [Department of Transportation](#)
- [Occupational Safety & Health Administration](#)
- [OSHA Field Inspection Reference Manual](#)
- [OSHA Technical Manual](#)

- [EPA - Guidance Materials for PMN Submitters](#)
- [TSCA Forms for Registration of New Chemicals](#)
- [Editable Notice of Commencement Form](#)
- [EPA Chemical Categories Document \(2002\)](#)

### TSCA Section 8(a) - Inventory Update Rule

- [2006 TSCA Inventory Update Reporting Instructions](#)

### TSCA Section 8(c) - Allegations of Significant Adverse Effects

- [DuPont TSCA Section 8\(c\) Allegation Form](#)
- [EPA's Guidance on Allegations of Significant Adverse Reactions](#)
- [TSCA Section 8\(c\) Presentation on Allegations of Effects Linked to Products](#)
- [TSCA 8\(c\) Refresher](#)
- [EPA's Question and Answers Concerning the TSCA Section 8\(c\) Rule](#)

### TSCA Section 8(e) - Substantial Risk Notification

- [TSCA Section 8\(e\) Corporate Process Overview](#)
- [TSCA Section 8\(e\) Haskell Potential Reportable Information Notification Form](#)
- [TSCA Section 8\(e\) Non-Haskell Potential Reportable Information Notification Form](#)
- [TSCA Section 8\(e\) Presentation on Substantial Risk Reporting - Biomonitoring and 8c Alle](#)
- [TSCA Section 8\(e\) Presentation on Substantial Risk Reporting - Commercial/Litigation Fo](#)
- [TSCA Section 8\(e\) Presentation on Substantial Risk Reporting - Environmental Focus](#)
- [TSCA Section 8\(e\) Presentation on Substantial Risk Reporting - Product Stewardship Foc](#)


### TSCA Section 12(b) - Export Notifications



## 4. How to Report Internally and to Whom?

The form looks like this, and includes instructions for submitting.

TSCA §8(e) Potential Reportable Notification  
& Reporting Decision (non-Haskell Form 01.01.09 revised)



TSCA Section §8(e) – Potential Reportable Notification (PRN) Form

**Instruction:** Complete all requested information on page 1 to the extent known or applicable. Information that is not known or is not applicable should be indicated as such in the appropriate box. Do not leave any boxes blank.

**Submit to:** Submit entire form (with page 1 completed) electronically to the Corporate TSCA §8(e) Review Team at the following e-mail address: <mailto:TSCA82@nanotes1.email.dupont.com>. The form may also be submitted to other personnel (such as, for example, line management, the TSCA SBU Coordinator, or the TSCA §8(e) Process Coordinator) as directed by a particular business. Contact information for the TSCA §8(e) Process Coordinator, and for the TSCA SBU Coordinators, is provided at <http://www1.fvs.dupont.com/SH/Emvstewdtscalpdf/tscacordinatorsnetwork.pdf>

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Date	
Submitter contact information	Name:
	Business:
	Phone number:
Chemical substance(s) or mixture(s) [composition(s) where possible], or process(s)	

#### *4. How to Report Internally and to Whom?*

- Submitting the form as instructed on the 1<sup>st</sup> page of the form ensures the information is received by the TSCA §8(e) Review Team and is entered into the Corporate TSCA §8(e) Review Process.
- The TSCA §8(e) Review Team members are listed on the 2<sup>nd</sup> page of the form. The Team is comprised of at least one representative from Haskell Laboratory, from the Corporate Safety, Health, and Environment and Sustainable Growth Center, and from Legal.
- The completed form should be promptly submitted to the TSCA §8(e) Review Team as the time period for reporting to EPA is generally 30 days.

## 5. *Penalties for Failure to Report*

Civil and/or criminal penalties may be assessed for failure to comply with TSCA §8(e) reporting requirements.

- The civil penalty can be the maximum allowable under TSCA, currently set at \$37,500 per day that the information is not reported.
- The criminal penalty is a fine of not more than \$37,500 per day and/or imprisonment for not more than one year.
- *Remember* – an employee who timely reports potential substantial risk information through the Corporate TSCA §8(e) Review Process is relieved of personal liability for failure to report that information to EPA (assuming it is required to be reported under TSCA §8(e)).

## 6. *Notifying the Submitter of the Reporting Decision and Rights under TSCA §8(e)*

- The TSCA §8(e) Review Team reviews the submitted Potential Reportable form within thirty (30) days of receipt of the completed form. A reporting decision is made within that thirty (30) day time period, provided all information needed to make the decision is available.
- The TSCA §8(e) Review Team documents the final reporting decision on page 2 of the Potential Reportable form. If reportable, the form indicates the date by which the information must be submitted to EPA.
- A copy of the completed form is provided electronically to the submitter of the form.
- The form provides notification to the submitter that *if the Corporate Review Team decides that the information is not reportable under TSCA §8(e), then the submitter is advised that the law guarantees the submitter the right to report the information directly to EPA without risk of discharge or discrimination concerning the terms, conditions, or privileges of employment.*

## *Summary*

- DuPont has established a system for reporting potential TSCA 8(e) substantial risk information.
- An employee who reports potential substantial risk information in a timely manner through the Corporate TSCA §8(e) Review Process is relieved of personal liability for failure to report that information to EPA.
- You will be notified of the reporting decision made by the Corporate TSCA 8(e) Review Team. If it is decided that the information is not reportable, you will be advised that the law guarantees you the right to report the information yourself directly to EPA without risk of discharge or discrimination concerning the terms, conditions, or privileges of employment.
- If in doubt about whether or not the information should be submitted for internal review by the Corporate TSCA 8(e) Review Team, then submit the information. It is better to over-report than to not report.